

REMARKS

Applicants respectfully request reconsideration of the pending claims in view of the foregoing amendments and the remarks that follow.

Status of the claims

Claims 1-102 were pending in the subject application. Claims 1-88 were previously withdrawn. Claims 89, 91 and 93 are amended. Support for the amendments to these claims can be found through out the specification, particularly, paragraphs [0035]-[0041], [0046]-[0048], [0051] and in the working examples and accompanying tables 1 and 2 respectively.

Upon entry of this communication, claims 89-102 are pending, rejected and presented for reconsideration.

Examiner Interview

Applicants thank Examiner Westerberg for granting an interview to Applicant's representatives on June 18, 2010. As disclosed on page 4 of the interview summary, there was a discussion to amend the independent claims to recite specific compounds for each component of the inventive method.

The Office Action

I. Double Patenting:

Claims 89, 91 and 93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 45, and 47-49 of co-pending U.S. Patent application No. 10/555310 in view of U.S. Patent No. 5,840,332. Applicants request the PTO to hold this rejection in abeyance until patentable subject matter has been identified.

II. Alleged Written Description Rejection

Claims 89-102 are alleged to not comply with the written description requirement under 35 USC §112-first paragraph. Applicants respectfully traverse.

Without acquiescing to the propriety of this rejection, Applicants have amended claims 89, 91 and 93 to recite species for each component of the burst release formulation used in the inventive methods. These amendments satisfy the written description requirement. Accordingly, the PTO is requested to withdraw the rejection.

III. The Claims Are Patentable Over Sherman in view of Lerner

A. Claims 89-99 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent Number 6,274,171 (Sherman *et al.*) in view of U.S. Patent Number 5,840,332 (Lerner *et al.*). Applicants respectfully traverse.

The present invention provides a method for providing extended release of venlafaxine by orally administering a composition that comprises a core and an outer coating.

As recited in the claims, the core of the inventive composition comprises (i) venlafaxine, or its pharmaceutically acceptable salt, (ii) at least one burst controlling agent selected from the group consisting of cross-linked polysaccharide, modified cellulose, calcium pectinate, and microcrystalline cellulose and (iii) a disintegrant selected from the group consisting of crospovidone, cross-linked sodium carboxymethyl cellulose, sodium carboxymethyl starch, microcrystalline starch, pregelatinized starch, water insoluble starch, calcium carboxymethyl cellulose, magnesium aluminum silicate and combinations thereof.

The outer coating of the inventive formulation comprises a water insoluble hydrophobic carrier and water-insoluble but hydrophilic particulate matter. As recited in the claims, the outer coating of the inventive formulation comprises ethylcellulose, microcrystalline cellulose, calcium pectinate and cetyl alcohol. The inventive formulation is suitable to provide a delayed burst release of venlafaxine *in vivo* at least two hours following administration.

None of the cited references teach or suggest a method for providing extended release of venlafaxine using an orally administerable formulation as claimed.

Sherman is cited by the PTO to teach an extended release composition that the Office alleges is the same as the claimed composition. However, this is not the case. Sherman discloses and exemplifies a formulation that contains spheroids of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropylmethyl cellulose (HPMC), which spheroids are coated with a mixture comprising ethylcellulose and HPMC in a 1:1 ratio. See example 1.

In sharp contrast, the specification describes and exemplifies an inventive formulation comprising venlafaxine, crospovidone (disintegrant), and burst control agents selected from calcium pectinate and/or microcrystalline cellulose as components of the core. The core of the inventive composition can optionally comprise other agents, such as binders, lubricants and flow regulating agents, as described in the working examples.

It is clear from the specification and working examples that the core of Sherman's composition has a different chemical make-up than the core of the inventive formulation. That is, Sherman discloses and exemplifies a core that comprises HPMC polymer, in addition to drug and microcrystalline cellulose. Additionally, there is no teaching or suggestion in Sherman for the use of a disintegrant as claimed, much less for the use of a disintegrant selected from the recited list.

Sherman's composition also differs in the compositional make-up of the coat that surrounds the disclosed core. As described in the specification and further exemplified by the working examples, the core of the inventive formulation is coated using a composition comprising calcium pectinate, ethylcellulose, microcrystalline cellulose and cetyl alcohol.

In addition, Sherman does not disclose a coat as claimed. More specifically, there is no teaching in Sherman for cetyl alcohol in the disclosed coating.

While the PTO admits that Sherman does not teach the water-insoluble but hydrophilic particulate matter present in the disclosed coat and cites Lerner to remedy this deficiency, Lerner fails to remedy the deficiencies of Sherman's composition. That is, the

combination of Lerner and Sherman fail to suggest a composition as claimed, comprising a core and a coating as claimed, let alone the recited methods of extended release.

Accordingly, claims 89, 91 and 93 and the claims that depend therefrom are patentable over the combined teachings of Sherman and Lerner, and the Office is respectfully requested to withdraw the obviousness rejection.

B. Claims 89-99 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent Number 6,274,171 (Sherman *et al.*) in view of U.S. Patent Number 5,840,332 (Lerner *et al.*), further in view of U.S. Patent Number 5,506,270 to *Upton et al.* (hereafter “Upton”). Applicants respectfully traverse.

As stated above, the combination of Sherman and Lerner would not have prompted the skilled artisan to arrive at the inventive composition, much less to arrive at the recited methods. Upton is cited to teach specific embodiments of the claimed composition used in the inventive methods, such as a teaching of a venlafaxine formulation having a dosage of 60 mg.

Even if it is assumed that the formulation provided by the combined teachings of Sherman and Lerner is modified so as to provide a 60 mg dose of venlafaxine, as suggested by the PTO, such a formulation would still fall outside the scope of the claimed methods because Upton fails to remedy the deficiencies of Lerner and Sherman. That is, even if Upton’s teaching of a venlafaxine dosage of 60 mg is incorporated in a formulation of Sherman that has Lerner’s water-insoluble particulate matter, as suggested by the PTO, the resultant venlafaxine formulation would still be different from the formulation recited in the claims.

Accordingly, the combination of Sherman, Lerner and Upton fail to defeat the patentability of the claimed invention. All pending claims are patentable and the PTO is respectfully requested to withdraw the obviousness rejections.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Should any issues remain that warrant attention, Applicants invite the examiner to contact the undersigned to advance the prosecution.

Respectfully submitted,

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By



FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4620
Facsimile: (202) 672-5399

Benjamin A. Berkowitz
Attorney for Applicants
Registration No. 59,349

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.